

REMARKS / ARGUMENTS

1. Response to Office Action

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted the substance of the Office Action in ***10-point bolded and italicized font***. Assignee's arguments immediately follow in regular font.

Claims 1, 3, 5, 7, 8, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagyszalanczy et al (6048363). Nagyszalanczy discloses a blood pump that continuously monitors during systole and diastole the flow rate and increases or decrease the pump speed based on the flow rate to achieve the proper pump operating point (e.g. columns 14-16, table 1, figures 22 and 23, etc.) and therefore will monitor diastolic pump flow and change the speed in response to the flow.

Assignee respectfully traverses. In short, the cited reference, U.S. Pat. No. 6,048,363 to Nagyszalanczy, does not disclose each and every limitation of the presently pending claims. More specifically, and without limitation, Nagyszalanczy does not disclose or teach monitoring or controlling a VAD based on the "diastolic VAD flow rate" as required by independent claims 1 and 7.

Claims 1 and 7 have been amended to make it plain that the flow rate that is monitored or received is the "diastolic VAD flow rate." The "diastolic VAD flow rate" is not the same as the diastolic flow rate of the prior art. As the application notes (paragraph [0043], emphasis added),

However, in patients who have been implanted with a left VAD there is generally positive flow through the VAD during both systole and diastole. This is because the implanted continuous flow VAD essentially adds a constant positive flow offset to the native heart's pulsatile flow contribution.

Therefore, ***the conventional definitions for systolic flow and diastolic flow must be modified*** to make them applicable to patients implanted with left VADs. Thus, the systolic flow rate is considered herein as the flow contribution above the mean flow

rate value, while the *diastolic VAD flow rate* is considered herein as *the VAD flow contribution below the mean VAD flow rate*. Peak systolic VAD flow rate is considered herein to be the maximum VAD flow rate value in the VAD flow rate waveform in one cardiac cycle and average peak systolic VAD flow rate is the average value of multiple peak systolic VAD flow rate values over several cardiac cycles. Similarly, peak diastolic VAD flow rate is considered herein to be the minimum VAD flow rate value in the VAD flow rate waveform in one cardiac cycle and average peak diastolic VAD flow rate is the average value of multiple peak diastolic VAD flow rate values over several cardiac cycles.

Nagyszalanczy does not disclose or teach monitoring or receiving the diastolic flow rate as a function of the mean flow rate (i.e., the “diastolic VAD flow rate”). Rather Nagyszalanczy only monitors the rise and fall of the normal blood rate. Because Nagyszalanczy fails to disclose at least this element of claims 1 and 7, it cannot render those claims unpatentable. Reconsideration and withdrawal of these rejections are requested.

Claims 3, 5, 8, 10 and 11 depend from claims 1 and 7 and, therefore, are patentable for at least the reasons presented with respect to claims 1 and 7. Reconsideration and withdrawal of these rejections are respectfully requested.

Claims 2, 4, 6, 9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagyszalanczy. Nagyszalanczy discloses the claimed invention except for monitoring the heart rate and changing/increasing the pump speed also in response to the changing/increasing heart rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pump system and method as taught by Nagyszalanczy, with monitoring the heart rate and changing/increasing the pump speed also in response to the changing/increasing heart rate since it was known in the art that pump systems and methods monitor the heart rate and change/increase the pump speed also in response to the changing/increasing heart rate in order to provide a conventional and easily implemented way to monitor the patients increased demand and provide the proper amount of pressure/flow/pumped blood to the patient based on the patients increased activity, such as exercising, walking, etc.

Claims 2, 4, 6, 9, 12 and 13 depend from claims 1 and 7 and, therefore, are patentable for at least the reasons presented above with respect to claims 1 and 7. Reconsideration and withdrawal of these rejections are respectfully requested.

2. New Claims 14 - 20

New claims 14 - 20 have been added herein. Support for new claims 14 and 15 may be found in the specification as originally filed, specifically at paragraph [0028]. Support for claims 17 and 18 may be found in the specification as originally filed, specifically at paragraph [0039], [0042] and [0043]. Support for claims 19 and 20 may be found in the specification as originally filed, specifically at paragraph [0045].

Assignee submits that for at least the reasons presented above with respect to claims 1 and 7, new claims 14 – 20 are likewise patentable.

3. Conclusion

Original claims 1 – 13 have been amended to make it plain that the flow rate at issue is the “diastolic VAD flow rate.” Claims 14 – 20 are newly presented. With this response, claims 1 – 20 are now pending in this application. Assignee respectfully submits that each claim is patentable, as detailed herein. A notice of allowance is respectfully requested.

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Amdt. Dated 10/15/2007
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Assignee thanks the Examiner for his consideration and effort on this case and submits that this application is now in condition for allowance. Assignee respectfully requests that a timely Notice of Allowance be issued.

Respectfully submitted,

LOCKE LORD BISSELL & LIDDELL LLP

By 

Albert B. Deaver, Jr.

Reg. No. 34,318

Tel.: (713) 226-1141

adeaver@lockelord.com